

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use INVOKANA safely and effectively. See full prescribing information for INVOKANA.

INVOKANA® (canagliflozin) tablets, for oral use  
Initial U.S. Approval: 2013

### RECENT MAJOR CHANGES

Indications and Usage (1)	07/2023
Dosage and Administration (2)	07/2023
Contraindications (4)	07/2023
Warnings and Precautions (5.1)	07/2023

### INDICATIONS AND USAGE

INVOKANA is a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (1)
- To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease (1)
- To reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria (1).

#### Limitations of Use:

- Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus (1)
- Not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m<sup>2</sup> (1)

### DOSAGE AND ADMINISTRATION

- Assess renal function before initiating and as clinically indicated (2.1)
- The recommended starting dose is 100 mg once daily, taken before the first meal of the day (2.2)
- Dose can be increased to 300 mg once daily in patients tolerating 100 mg once daily who have an eGFR of 60 mL/min/1.73 m<sup>2</sup> or greater and require additional glycemic control (2.2)
- Dose adjustment for patients with renal impairment may be required (2.3)
- See full prescribing information for INVOKANA dosage modifications due to drug interactions (2.4)
- Withhold INVOKANA at least 3 days, if possible, prior to major surgery or procedures associated with prolonged fasting (2.5).

### DOSAGE FORMS AND STRENGTHS

Tablets: 100 mg, 300 mg (3)

### CONTRAINDICATIONS

- Serious hypersensitivity reaction to INVOKANA (4)

### WARNINGS AND PRECAUTIONS

- **Diabetic Ketoacidosis in Patients with Type 1 Diabetes Mellitus and Other Ketoacidosis:** Consider ketone monitoring in patients at risk for

ketoacidosis, as indicated. Assess for ketoacidosis regardless of presenting blood glucose levels and discontinue INVOKANA if ketoacidosis is suspected. Monitor patients for resolution of ketoacidosis before restarting (5.1)

- **Lower Limb Amputation:** Consider factors that may increase the risk of amputation before initiating INVOKANA. Monitor patients for infection or ulcers of lower limb and discontinue if these occur (5.2)
- **Volume Depletion:** May result in acute kidney injury. Before initiating INVOKANA, assess and correct volume status in patients with renal impairment, elderly patients, or patients on loop diuretics. Monitor for signs and symptoms during therapy (5.3)
- **Urosepsis and pyelonephritis:** Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated (5.4)
- **Hypoglycemia:** Consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia when used in combination with INVOKANA (5.5)
- **Necrotizing fasciitis of the perineum (Fournier's gangrene):** Serious, life-threatening cases have occurred in both females and males. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment (5.6)
- **Genital mycotic infections:** Monitor and treat if indicated (5.7)
- **Hypersensitivity reactions:** Discontinue INVOKANA and monitor until signs and symptoms resolve (5.8)
- **Bone fracture:** Consider factors that contribute to fracture risk before initiating INVOKANA (5.9)

### ADVERSE REACTIONS

Most common adverse reactions (5% or greater incidence): female genital mycotic infections, urinary tract infection, and increased urination (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Janssen Pharmaceuticals, Inc. at 1-800-526-7736 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### DRUG INTERACTIONS

See full prescribing information for information on drug interactions and interference of INVOKANA with laboratory tests. (7)

### USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Advise females of the potential risk to a fetus especially during the second and third trimesters (8.1)
- **Lactation:** Not recommended when breastfeeding (8.2)
- **Geriatrics:** Higher incidence of adverse reactions related to reduced intravascular volume (8.5)
- **Renal impairment:** Higher incidence of adverse reactions related to hypotension and renal function (8.6)
- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment (8.7)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 07/2023

## FULL PRESCRIBING INFORMATION: CONTENTS\*

<b>1</b>	<b>INDICATIONS AND USAGE</b>
<b>2</b>	<b>DOSAGE AND ADMINISTRATION</b>
2.1	Prior to Initiation of INVOKANA
2.2	Recommended Dosage and Administration
2.3	Recommended Dosage in Patients with Renal Impairment
2.4	Concomitant Use with UDP-Glucuronosyl transferase (UGT) Enzyme Inducers
2.5	Temporary Interruption for Surgery
<b>3</b>	<b>DOSAGE FORMS AND STRENGTHS</b>
<b>4</b>	<b>CONTRAINDICATIONS</b>
<b>5</b>	<b>WARNINGS AND PRECAUTIONS</b>
5.1	Diabetic Ketoacidosis in Patients with Type 1 Diabetes Mellitus and Other Ketoacidosis

5.2	Lower Limb Amputation
5.3	Volume Depletion
5.4	Urosepsis and Pyelonephritis
5.5	Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues
5.6	Necrotizing Fasciitis of the Perineum (Fournier's Gangrene)
5.7	Genital Mycotic Infections
5.8	Hypersensitivity Reactions
5.9	Bone Fracture
<b>6</b>	<b>ADVERSE REACTIONS</b>
6.1	Clinical Studies Experience
6.2	Postmarketing Experience
<b>7</b>	<b>DRUG INTERACTIONS</b>













































































































